Department of Health and Human Services
Centers for Disease Control and Prevention (CDC)
Division of Select Agents and Toxins (DSAT)
Atlanta, Georgia

United States Department of Agriculture
Animal and Plant Health Inspection Service (APHIS)
Agriculture Select Agent Services (AgSAS)
Riverdale, Maryland

TO: Unified Command, Louisiana State Governor's Office of Homeland Security & Emergency Preparedness

FROM: Directors, Federal Select Agent Program

DATE: March 13, 2015

SUBJECT: Federal Select Agent Program Investigation of the *Burkholderia pseudomallei* release at the Tulane National Primate Research Center

The Federal Select Agent Program (the HHS CDC Division of Select Agents and Toxins and the USDA APHIS Agriculture Select Agent Services) (FSAP) conducted an investigation of an incident at Tulane National Primate Research Center (TNPRC) in Covington, Louisiana in which multiple non-human primates (NHP) from the TNPRC breeding colony became infected with a laboratory strain of the Tier 1 select agent, *Burkholderia pseudomallei*. Since these NHPs were housed in outdoor field pens that are not registered with the FSAP, the goals of this investigation were: to determine how *B. pseudomallei* was released from the laboratory, to identify any violations of the select agent regulations (9 CFR Part 121, 42 CFR Part 73) associated with this release, and to assist the TNPRC in making safety and security improvements to prevent the recurrence of similar incidents in the future. This report summarizes the Federal Select Agent Program investigation, and does not include information from other ongoing State and Federal investigations.

What Happened

On December 11, 2014, TNPRC notified the FSAP of a suspected infection with *B. pseudomallei* in two NHPs housed in the TNPRC NHP breeding colony. Although TNPRC is registered with the FSAP to work with *B. pseudomallei*, the breeding colony is not included in the TNPRC select agent registration and none of the NHPs in this colony should have had the opportunity to become infected with this agent. TNPRC submitted samples from the infected NHPs to the CDC for additional testing and these samples were found to be positive for a strain of *B. pseudomallei* being used in a TNPRC select agent laboratory. On December 18, 2014, TNPRC submitted an APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins), which notified the FSAP of the potential release of *B. pseudomallei*. On December 30 and January 14, laboratory results from tests conducted by the CDC confirmed that the isolates of *B. pseudomallei* found in two infected NHPs were identical to each other, and to a laboratory strain that TNPRC reported using in their select agent research laboratory. Beginning January 21, 2015, the FSAP initiated a series of site visits to the TNPRC to investigate this incident and on February 2, 2015 additional resources from the CDC National Center for Emerging and Zoonotic Infectious Diseases, the CDC National Center for Environmental Health, the CDC National Institute for Occupational Safety and Health, the USDA Veterinary Services, and the Environmental Protection Agency were sent to provide assistance to the State of Louisiana concerning this incident. An overall unified command structure was established by the Louisiana Governor's Office of Homeland Security & Emergency Preparedness. On February 11, 2015 the FSAP suspended all select agent activities at TNPRC.

At this time two likely routes of transmission from the laboratory to the infected NHPs have been identified. They are not mutually exclusive. These are (1) exposure to the agent in their outdoor

enclosures within the breeding colony and/or (2) while being treated for unrelated illnesses in the TNPRC veterinary clinic. Both of the initial NHPs that were infected with *B. pseudomallei* were held in the clinic until they were euthanized. Subsequent serologic testing of the cohorts of these animals revealed that additional NHPs have been exposed to *B. pseudomallei*. These animals share histories of being in the clinic with the two index NHPs. The ongoing federal and state investigation is addressing this issue, and subsequent public health, agricultural, and environmental concerns.

How the Incident Happened

The specific transmission event from the laboratory to the infected NHPs has not been identified; however, plausible mechanisms were uncovered during the investigation. The FSAP investigators discovered a number of lapses in the management of personal protective equipment (PPE) and implementation of biosafety practices and security procedures in the building where *B. pseudomallei* is manipulated and stored. For example, the misuse of outer gowns, which could have allowed inner garments to become contaminated. These lapses establish plausible mechanisms for the contamination of workers or items transported by workers who have access to the select agent laboratory and other locations on the TNPRC campus, including the clinic and breeding colony. The TNPRC has since implemented a shower out procedure which requires all clothing and PPE worn while inside their select agent laboratories to be disposed of as biohazardous waste, and not worn to other areas of the TNPRC campus.

In addition, FSAP investigators discovered that TNPRC did not have adequate plans or policies to effectively respond to this incident. FSAP investigators found that TNPRC did not fully implement the procedures described in their occupational health plan, which contributed to a delay in identifying and notifying individuals of their exposure risk and subsequent medical surveillance and counseling. Also, TNPRC biosafety and security procedures did not adequately address the management of animals not involved in select agent research that were accidentally exposed to or infected with a select agent. As such, TNPRC actions in response to the infection of the NHPs with *B. pseudomallei* did not effectively take into account the biosafety or security concerns with this select agent.

What Has the FSAP Done Since the Incident Occurred

In response to the incident, the FSAP has taken the following steps:

1. Suspended all select agent activities at the TNPRC pending the implementation of corrective actions to prevent the occurrence of similar incidents in the future;
2. Performed a 100% verification of all *B. pseudomallei* inventory possessed by TNPRC;
3. Reviewed TNPRC's current biosafety (including occupational health), incident response, and security procedures;
4. Examined records of personnel access for the TNPRC laboratories registered with the FSAP, veterinary clinic and breeding colony;
5. Reviewed surveillance camera footage covering the entrances of the TNPRC laboratories registered with the FSAP;
6. Interviewed TNPRC personnel who work in the TNPRC select agent laboratories, veterinary clinic and breeding colony;
7. Observed TNPRC personnel demonstrate donning and doffing procedures for personal protective equipment to evaluate donning and doffing technique; and
8. Reviewed with the FBI Weapons of Mass Destruction Directorate personal reliability information on individuals associated with this release. No criminal nexus has been identified.

What Corrective Actions Are Recommended Moving Forward

Recommendations for TNPRC moving forward:

1. Develop entity-wide procedures to ensure that animals that are accidentally exposed to or infected with a select agent are managed so that biosafety and security considerations and the hazards associated with the select agent are taken into account;
2. Thoroughly review all current procedures related to PPE management, biosafety, occupational health, and security, and based upon that review, revise those procedures to mitigate the risk of breaches occurring;
3. Provide training to all TNPRC personnel on the revised PPE management, biosafety, including occupational health, and security procedures to ensure understanding of updated procedures and compliance with implementation of those procedures; and
4. Upgrade PPE and entrance/exit procedures from outside enclosures that house infected animals as suggested by FSAP inspectors in the January site visit until the extent of environmental contamination is known.

The current suspension of all select agent activities at TNPRC will remain in force until all findings in inspection report are remediated and all recommendations are addressed. The ongoing Federal and State investigation of this incident may result in additional recommendations as additional information is developed. The FSAP is referring this case to enforcement bodies within USDA and/or HHS for consideration of civil money penalties and other administrative actions.

Robbin S. Weyant, PhD, RBP (ABSA)
Captain, USPHS (Ret.)
Director, Division of Select
Agents and Toxins
Department of Health and Human
Services
Centers for Disease Control and
Prevention

Freeda E. Isaac, DVM
Director, Agriculture Select Agent
Services
United States Department of
Agriculture
Animal and Plant Health
Inspection Service